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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/171,432    11/23/98    FIELDS    H    03063-0231US

023859  
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127 PEACHTREE STREET N E  
ATLANTA GA 30303-1811

HM12/0515

EXAMINER

BRUMBACK, B

ART UNIT

PAPER NUMBER

1642

DATE MAILED:

05/15/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/171,432

Applicant(s)

Fields et al.

Examiner

Brenda Brumback

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Mar 28, 2001
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1 and 69-76 is/are pending in the application.
- 4a) Of the above, claim(s) 1, 69, and 73-76 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 70-72 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Election/Restriction***

1. Applicant's election of Group II, claims 70-73, and species election of the P2A protein of HAV corresponding to amino acids 792-980 (SEQ ID NO's: 39-46) in Paper No's. 11, 16, and 20 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 1 and 69-76 are pending. Claims 1, 69, and 74-76 are withdrawn from consideration as directed to a nonelected invention. Claim 73 is withdrawn from consideration as directed to a nonelected species. Claims 70-72 are under examination to the extent that they read on the elected species, the P2A protein of HAV corresponding to amino acids (AA) 792-980, SEQ ID NO's:39-46.

### ***Priority***

3. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) since the oath or declaration does not acknowledge the filing of Provisional Application No. 60/015,644. A new oath or declaration is required identifying the provisional application by application number and filing date.

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Furthermore, an application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78). Since the present case is a national stage application of PCT/US97/06891, which claims priority to provisional application 60/015,644; the statement should also reference the international application for continuity.

***Information Disclosure Statement***

4. The Information Disclosure Statement filed 11/23/1998 (Paper # 6) is acknowledged. A signed copy is attached hereto.

***Specification***

5. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

***Claim Rejections - 35 USC § 112***

6. Claims 70-72 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 70 recites an "HAV" peptide. It is suggested that the full name of the virus for which HAV is an acronym be written out at the first occurrence in the claims, followed by the abbreviation, such as "hepatitis A virus (HAV)".

Claim 70 recites an amino acid sequence which is "substantially similar" to a "portion" of an HAV protein selected from the P2A protein of HAV, among others. The terms "substantially" and "similar" are relative terms which render the claim indefinite. The terms "substantially" and "similar" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The term "portion" renders the claim indefinite because the metes and bounds of such a "portion" are not taught in the disclosure. It is also unclear if the portion of the protein claimed is a portion of the HAV polypeptide corresponding to the P2A protein, or if the portion of the protein claimed is a portion of the P2A protein. Additionally, the claim recites the HAV protein as corresponding to AA "792 to about 980". The term "about" renders the claim indefinite, because the upper limit of the AA range cannot be ascertained. Furthermore, the claim recites SEQ ID NOS: 11-72 and conservative variations thereof. While the disclosure delineates what is encompassed within conservative amino acid substitutions (see page 13), it is not clear that "conservative variations" is intended to have the same meaning. Lastly, it is unclear to what sequence "amino acids 792 to about 980" is referring. Absent recitation of the specific sequence (either by SEQ ID NO. or by a sequence name which is

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supported by a specifically recited sequence in the specification) the claim is indefinite.

Correction is required.

*Claim Rejections - 35 USC § 103*

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 70-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chiron Corporation (EPA 0 199 480; of record in paper # 6).

Although indefinite for the reasons set forth *supra*, the claimed invention has been interpreted as drawn to an isolated immunogenic peptide comprising an amino acid sequence corresponding to AA 792-980 of the polyprotein of HAV (the P2A protein) which binds to an antibody that is specifically immunoreactive with a peptide selected from the group consisting of SEQ ID NO:11 - SEQ ID NO:72.

Chiron teaches the entire genome of the HAV, including AA 792-980, and teaches epitopes of the HAV polyprotein which are immunogenic (see the abstract and Fig. 1). Chiron teaches the predicted P2A protein as roughly corresponding to AA 837-980 of the polyprotein (see Fig. 1b). Chiron teaches a preferred immunogenic peptide as derived from AA 792-848 (see

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page 18, claim 14). One of ordinary skill in the art at the time the invention was made would have found it *prima facie* obvious to have made an immunogenic peptide according to the AA sequence taught by Chiron and to have included AA 792-848 as a preferred epitope in the peptide, according to the teachings of Chiron.

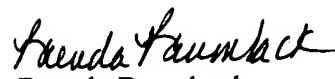
*Conclusion*

8. No claims are allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Brumback whose telephone number is (703) 306-3220. If the examiner can not be reached, inquiries can be directed to Supervisory Patent Examiner Anthony Caputa whose telephone number is (703) 308-3995. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Examiner Brenda Brumback, Art Unit 1642 and should be marked "OFFICIAL" for entry into prosecution history or "DRAFT" for consideration by the examiner without entry. The Art Unit 1642 FAX telephone number is (703)-305-3014. FAX machines will be available to receive transmissions 24 hours a day. In compliance with 1096 OG 30, the filing date accorded to each OFFICIAL fax transmission will be determined by the FAX machine's stamped date found on the last page of the transmission, unless that date is a Saturday, Sunday or Federal Holiday with the District of Columbia, in which case the OFFICIAL date of receipt will be the next business day.

BB

May 15, 2001

  
Brenda Brumback,  
Patent Examiner